Keeping Drug Advertising Honest and Balanced

Each year, drug companies spend about $25 billion in the United States promoting their prescription medications. Most goes to promoting drugs to health care professionals, but a growing amount—about one-fifth—is spent on direct-to-consumer (DTC) advertising.

Thomas Abrams is the director of the Office of Prescription Drug Promotion (OPDP) at the Food and Drug Administration (FDA)(*www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ucm090142.htm*). He talks about how FDA protects consumers from false or misleading ads for prescription drugs that appear on TV, radio, online, and in print publications.

Q: The United States and New Zealand are the only countries where prescription drug advertising is directed at consumers. Why is it allowed?

A: The First Amendment provides for freedom of speech, including commercial speech by companies. Direct-to-consumer advertising is considered commercial speech. FDA is charged by law to make sure advertising and other promotional materials are accurate and balanced, and provide helpful information to consumers about medical conditions and drugs to treat them.

Q: Do people at OPDP actually watch drug commercials?

A: Yes, we do. Drug companies are required to submit to our office all advertisements and other promotional materials at the time they make them public. Some companies submit materials to us for advisory comments before they make them public.

We receive anywhere from 6,000-8,000 pieces of advertising and promotional submissions each month. The materials are assigned to one of our 32 reviewers, who specialize in specific drug categories, such as asthma medicines or cardiac (heart) treatments. Many reviewers are health care professionals with diverse backgrounds in academia, industry, hospitals and pharmacies. They use a risk-based approach that allows them to prioritize their work to quickly identify promotional materials with the most potential for negative impact on public health.

Q: What happens when a reviewer finds something like this? Isn't the material already public?

A: The first step is to review the promotion and take action if needed. Most often we issue enforcement letters, which ask that companies stop the misleading promotion. We can take additional actions if the misleading promotion is not discontinued, including legal actions through the Justice Department.

Q: What would make an ad false or misleading?

A: If the ad states that the drug is more effective or has fewer or less severe side effects than has been demonstrated, we'd consider that false or misleading. Same thing if the ad claims, without solid evidence, that the product is safer or more effective than a competitor's drug, or if it misrepresents the product's risks. We also pay careful attention to balance, making sure the risks are displayed prominently so that they can be read, heard and understood easily.

Q: Has social media complicated the job?

A: It certainly has. The Internet and social media have increased the volume and extent of materials and speeded the delivery of those materials. Websites can have hundreds of pages and can change daily.

It is important to know that although we closely monitor what companies say, we generally do not have authority over statements made by independent organizations or persons—what we call third parties—unless they are acting on behalf of a company.

Q: Have you taken any actions against drug advertising on social media?

A: Yes, we have acted against misleading promotional materials disseminated by companies using social media platforms such as YouTube and Facebook. For instance, we sent a warning letter to a company that developed and posted a video testimonial promoting its drug on YouTube. The testimonial featured a well-known TV celebrity. The warning letter noted, among other things, that the promotional testimonial violated the regulations by overstating the benefits of the drug product and not mentioning the serious risks of using the product. The company removed the ad and complied with our request to create a plan of action to disseminate truthful information to audiences exposed to the promotion.

Q: Do you ever hear from other companies or consumers about misleading or unbalanced promotional materials?

A: Absolutely, and we encourage everyone to watch for it and let us know if they see misleading or unbalanced prescription drug promotion. We have posted information on how to notify us on our Bad Ad web page (*www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ucm090142.htm*). We receive several hundred complaints each year from consumers, health care professionals and companies' competitors.

Q: Do you review ads for over-the-counter (OTC) drugs too?

A: No, we do not. The Federal Trade Commission (FTC) has primary jurisdiction over OTC ads. Other groups in FDA have primary jurisdiction over OTC product labeling and work closely with FTC on the regulation of OTC promotion.

Q: After working as a pharmacist, earning an MBA, and working in pharmaceutical companies, you came to FDA 19 years ago. Have things changed a lot during your tenure?

A: Immensely. The area of prescription drug promotion is such a dynamic one. When I first started at FDA, there was very little prescription drug promotion on television or the Internet. The number of vehicles and ways that companies promote their products has increased significantly, as well as the amount of promotion. The office at FDA has had to grow with it.

I'm passionate in my efforts to prevent patients from being misled. I am extremely fortunate to have high-caliber, hard-working people in OPDP who are deeply committed to promoting public health. We all believe it is critical that patients receive good, useful, balanced information about the prescription products they use.

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